MAY 1 1982

GA 1.13 : HRD-82-41/sum.

546-D

BY THE COMPTROLLER GENERAL

Report To The Congress

OF THE UNITED STATES

FDA's Approach To Reviewing Over-The-Counter Drugs Is Reasonable, But Progress Is Slow

SUMMARY

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Federal law requires the Food and Drug Administration to ensure that drugs sold over the counter are safe and effective. FDA has designed a reasonable approach to regulating this large market, where retail sales are estimated to be $5.2 billion annually.

However, despite reports by scientific panels that many drug ingredients currently marketed are unsafe or ineffective, FDA has been slow in developing and publishing regulations, called monographs, for the formulation and labeling of these drugs. After 10 years, regulations for only 4 of 84 categories of drugs have been issued. Enforcement of monographs may also become a problem.

This report discusses actions that could help speed the review process and improve enforcement.

HRD-82-41
APRIL 23, 1982

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COMPTROLLER GENERAL'S
REPORT TO THE CONGRESS

FDA'S APPROACH TO REVIEWING OVER-THE-COUNTER DRUGS IS REASONABLE, BUT PROGRESS IS SLOW

D I G E S T

Are the 200,000 to 300,000 products marketed as over-the-counter (OTC) drugs safe and effective? Although the Food and Drug Administration (FDA) has been reviewing these products since 1972, it has published regulations--called monographs--for only 4 of 64 categories of drug products. FDA estimates that it will be 1990 before all the monographs are published.

In view of the size of the task it faced, FDA adopted a reasonable review process, but it is taking much longer than planned. GAO's review found problems similar to those found in earlier reviews of FDA's procedures for approving new drugs. Some of the same type of actions taken by FDA to speed up new drug approvals could be applied to the OTC drug review.

FDA'S APPROACH--
REASONABLE BUT TIME CONSUMING

FDA's strategy for reviewing OTC drugs is reasonable. It involves making a scientific analysis of available data and setting standards of safety and effectiveness for each ingredient used in classes of drugs, such as antacids or internal analgesics (pain relievers), instead of reviewing each OTC product individually. (See p. 5.)

The OTC review process consists of three phases: review of scientific data by expert advisory panels, review of panel findings and drafting and publishing of monographs by FDA, and enforcement of the monographs by FDA. (See p. 1.)

In 10 years, FDA has completed only 4 of 64 planned final regulations. Average processing time has risen despite greatly increased staff. In 1975, FDA estimated that it would take 15 months to publish a final monograph after the panel report was received. In 1980, this estimate had increased to 72 months for a short monograph and 108 months for a long monograph. (See p. 7.)

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The review has resulted in unsafe or ineffective products--such as those containing methapyrilene, a potential carcinogen--being removed from the market. Also, products have been voluntarily reformulated and relabeled, and some drugs that previously were available only by prescription are now sold over the counter. (See p. 11.)

However, most of the review's expected benefits have not yet been realized. Having reviewed the safety and effectiveness of 731 ingredients with 1,393 uses (see footnote, p. 12), the panels concluded that a third of the ingredient uses were unsafe or ineffective and another third lacked sufficient evidence that the ingredients were safe and effective. Many of the drug products containing those ingredients will have to be relabeled or reformulated. (See p. 12.)

FACTORS DELAYING COMPLETION OF THE OTC REVIEW

The review turned out to be a much larger task than anticipated. But other factors related to planning and managing the monograph process have contributed to the delays. Specifically:

--Milestone dates for completing monograph documents were not based on priorities, not sufficiently detailed, and not based on actual experience. Priorities that were set had little meaning.

--Status reports either were not used to track progress in completing monograph documents or did not compare results to projected milestones.

--Policy decisions often were not made promptly.

--The office of the Director of FDA's Division of Over-the-Counter Drug Evaluation had taken over functions related to monograph development that were supposed to be the responsibility of the division's four branches. As a result, the monograph documents got bogged down in the Director's office while staff in the branches were not effectively used. (See pp. 13 to 18.)

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MONOGRAPH ENFORCEMENT HAMPERED BY LACK OF ACCURATE LISTING OF OTC DRUGS AND INADEQUATE MONITORING

FDA has implemented two pilot compliance programs. GAO's review of these programs indicated several potential problems for future OTC compliance efforts. For example, the antacid compliance effort was begun in 1976, yet as of January 1982, FDA had not completed its initial review of the identified products. It took FDA about 3 years to identify products subject to the monograph, but it still does not know if it has identified all the products on the market.

The problems were caused by (1) the lack of an accurate listing of OTC drugs, which caused FDA to use the lengthy process of searching catalogs and visiting manufacturers to locate products, and (2) FDA's failure to adequately monitor or evaluate enforcement efforts. (See p. 22.)

RECOMMENDATIONS TO THE SECRETARY OF HEALTH AND HUMAN SERVICES

The Secretary should direct the Commissioner of FDA to:

--Establish priorities for completing individual monographs based on objective criteria, such as consumer sales or market impact, and establish detailed milestones for completing the development of monographs and the publication of final regulations based on actual experience, staff skills and experience, the work required, and the priority of the monograph document.

--Establish goals for expediting the OTC review and develop a system for measuring progress in completing all monograph documents which measures progress against projected milestones and provides feedback to FDA and the Department.

--Develop a mechanism for high-level agency officials to promptly identify and resolve policy issues.

--Review, and revise where appropriate, procedures for reviewing draft monograph documents to ensure that branch personnel are given necessary supervision and authority to develop the products for which they are responsible.

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--Determine, based on the anticipated cost and timeliness of alternative approaches, whether the OTC drug listing files are needed. If the listing is not needed, FDA should propose legislation to amend the Drug Listing Act to eliminate the reporting requirement. If it is needed, FDA should assess the relative efficiency of updating the entire system in the next few years or updating the system by drug category as monographs are published.

--Establish measurable objectives for the OTC enforcement effort and the expected timetables for performing the work.

--Maintain for each category of drug product a complete master list of firms manufacturing the drug and a list of products as they are identified for each monograph.

--Track the progress made in reviewing and following up on products subject to the monographs and highlight, through written reports or regular meetings with district representatives, problems encountered in enforcing monographs. (See pp. 19 and 28.)

AGENCY COMMENTS AND GAO EVALUATION

The Department of Health and Human Services (HHS) agreed with the intent of the GAO recommendations and pointed out a number of corrective actions that had been or were being taken.

HHS did not, however, respond to a major portion of one recommendation which would establish detailed milestones for completing the development of monographs. GAO believes that FDA management needs such milestones to assess progress being made in developing the monograph documents.

GAO also believes that FDA needs to take additional action on several of the recommendations. For example, on the recommendation that goals be established for completing the OTC review, FDA does have short-term goals for some of the monograph documents in the annual merit pay and senior executive service contracts of supervisors and managers.

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While these goals are a step in the right direction, they do not include all the monographs. Moreover, additional long-term goals are needed. (See pp. 19 and 29.)

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This review was made because earlier GAO work indicated that FDA was taking an inordinate length of time to complete the project. GAO wanted to determine why the review was taking so long and what steps could be taken to expedite it.

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ABBREVIATIONS

FDA	Food and Drug Administration
GAO	General Accounting Office
HHS	Department of Health and Human Services
OTC	over-the-counter

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